

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

|                                    |   |                     |
|------------------------------------|---|---------------------|
| _____                              | ) |                     |
| TALECRIS BIOTHERAPEUTICS, INC.,    | ) |                     |
|                                    | ) |                     |
| Plaintiff                          | ) |                     |
|                                    | ) |                     |
| v.                                 | ) |                     |
|                                    | ) | C.A. No. 05-349 GMS |
| BAXTER INTERNATIONAL INC., et al., | ) |                     |
|                                    | ) |                     |
| Defendants                         | ) |                     |
| _____                              | ) |                     |
|                                    | ) |                     |
| BAXTER HEALTHCARE CORP.,           | ) |                     |
|                                    | ) |                     |
| Counterclaimant                    | ) |                     |
|                                    | ) |                     |
| v.                                 | ) |                     |
|                                    | ) |                     |
| TALECRIS BIOTHERAPEUTICS, INC.     | ) |                     |
| and BAYER HEALTHCARE LLC,          | ) |                     |
|                                    | ) |                     |
| Counterdefendants                  | ) |                     |
| _____                              | ) |                     |

**ORDER CONSTRUING THE TERMS OF U.S. PATENT NO. 6,686,191**

After having considered the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent No. 6,686,191 (the “‘191 patent”):

1. The term “any virus activity” is construed to have its plain and ordinary meaning.<sup>1</sup>
2. The term “under conditions ... resulting in an increased level of anticomplement activity” is construed to have its plain and ordinary meaning.<sup>2</sup>
3. The term “under conditions sufficient to substantially reduce any virus activity and resulting in an increased level of anticomplement activity” is construed to have its plain and ordinary meaning.<sup>3</sup>
4. The term “increased level of anticomplement activity” is construed to have its plain and ordinary meaning.<sup>4</sup>
5. The term “increased anticomplement activity of the solution” is construed to have its plain and ordinary meaning.<sup>5</sup>

---

<sup>1</sup> “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (citing *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001)).

<sup>2</sup> The Defendants’ alternative construction invites the court to import a limitation from the preferred embodiment into the claims, which is contrary to Federal Circuit precedent. *See Comarck Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998) (“[w]hile . . . claims are to be interpreted in light of the specification and with a view to ascertaining the invention, it does not follow that limitations from the specification may be read into the claims.”). Further, “when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims.” *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

<sup>3</sup> See footnote 2.

<sup>4</sup> The Defendants’ construction invites the court to import a limitation from the preferred embodiment into the claims. See footnotes 1 and 2. Further, “nor may [the court], in the broader situation, add a narrowing modifier before an otherwise general term that stands unmodified in a claim.” *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

<sup>5</sup> See footnote 4.

6. The term “then incubating the solution of step a)” is construed to mean “incubating a solution originating from step a) under conditions of controlled time, pH, temperature, and ionic strength, wherein additional steps may be performed prior to said incubating.”<sup>6</sup>
7. The term “about 60 CH<sub>50</sub> units/mL” is construed to mean “about 60 CH<sub>50</sub> units/mL, wherein one unit of ACA activity (one CH<sub>50</sub> unit) is defined as the amount of protein capable of activating 50% of the complement in an optimally titrated complement and red blood cell hemolysin system.”<sup>7</sup>
8. The term “about 45 CH<sub>50</sub> units/mL” is construed to mean “about 45 CH<sub>50</sub> units/mL, wherein one unit of ACA activity (one CH<sub>50</sub> unit) is defined as the amount of protein capable of activating 50% of the complement in an optimally titrated complement and red blood cell hemolysin system.”<sup>8</sup>

---

<sup>6</sup> The specification contemplates removal of solvent and detergent molecules after incubation in step a). ‘191 patent, 4:43-45. The specification provides that “[v]ery low levels of TNBP and cholate in the final container can be achieved by a combination of filtration, diafiltration and hydrophobic chromatography.” ‘191 patent, 4:49-51. The specification describes, in 4:66 - 5:41, various steps to achieve tonic adjustment and to lower the amount of solvent and detergent molecules. Thereafter, the specification states “[t]he so-treated solution [4:66 - 5:41] is incubated ... in order to provide a lowering of ACA levels.” ‘191 patent, 5:43-44. Therefore, to construe the claim terms as the Defendants propose would be contrary to the specification. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003) (“A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification, of which they are a part.”) (citations omitted).

<sup>7</sup> See the ‘191 patent, 5:64 - 6:1.

<sup>8</sup> See footnote 7.

9. The term “anticomplement activity” is construed to mean “the measure of the ability of antibodies to bind complement.”<sup>9</sup>
10. The term “acceptable level suitable for intravenous administration” is construed to have its plain and ordinary meaning.<sup>10</sup>
11. The term “ionic strength” is construed to mean “the summation:  $I=1/2\sum(c_i z^2)$  where  $c_i$  is the concentration of each type of ion (in moles l-1) and  $z$  is its charge.”<sup>11</sup>

Dated: December 28, 2006

/s/ Gregory M. Sleet  
UNITED STATES DISTRICT JUDGE

---

<sup>9</sup> See footnote 2.

<sup>10</sup> See footnote 2.

<sup>11</sup> The parties agree on the construction of “ionic strength.” See Joint Claims Construction Statement (D.I. 159).